

JUL 14 2005



U.S. Department
of Transportation

400 Seventh Street, S.W.
Washington, D.C. 20590

**Pipeline and
Hazardous Materials
Safety Administration**

DOT-E 14172

EXPIRATION DATE: June 30, 2007

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Pacific Bio-Material Management, Inc.
dba Pacific Scientific Transport
Fresno, CA
2. PURPOSE AND LIMITATION:
 - a. This exemption authorizes the transportation in commerce of certain materials (infectious substances and diagnostic specimens) in special packagings by Pacific Bio-Material Management, Inc. This exemption provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
 - b. The safety analyses performed in development of this exemption only considered the hazards and risks associated with transportation in commerce.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR §§ 173.196 (a) and (b), and 173.199(a) and (b) in that alternative packaging is not authorized, except as specified herein.
5. BASIS: This exemption is based on the application of Pacific Bio-Material Management, Inc. dated March 8, 2005, submitted in accordance with § 107.105 and the public proceeding thereon.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Infectious substances, affecting humans*	6.2	UN2814	n/a
Infectious substances, affecting animals only*	6.2	UN2900	n/a
Diagnostic specimen * **	6.2	n/a **	n/a

*Limited to Risk Groups 2 and 3, as defined in 49 CFR § 173.134(a)(6), revised as of October 1, 2004. Risk Group 4 materials are not authorized for transport under this exemption.
 **UN3373 is assigned to this material in the UN Model Regulations and the ICAO Technical Instructions.

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Materials, as listed in Paragraph 6, that are transported in freezers must conform to the following provisions:

(1) Materials must be packed in watertight primary receptacles (2 mL and/or 8 mL vials). Receptacles must be secured in individual cells of stainless steel boxes. Boxes must be secured in stainless steel racks. A rack holds from 10 to 13 boxes. The outer packaging must be a large capacity, commercial grade, double-walled, stainless steel, liquid nitrogen-cooled freezer (either a MVE Model 1830HE freezer or a Taylor Wharton Model LABS 80K freezer). Racks must be secured in sectors of the freezer to prevent tipping or shifting of the racks. Sufficient absorbent material must be placed in the freezer to absorb the entire contents of all primary receptacles in case of breakage or leakage. The freezer may contain approximately 40,000 2 mL vials or 15,000 8 mL vials, and approximately 100 liters of liquid nitrogen.

(2) Each freezer lid must be securely closed to prevent opening during transport.

(3) Materials in each freezer must be kept frozen at all times within the operating temperature range of -130 °C to -200 °C using liquid nitrogen.

b. OPERATIONAL CONTROLS -

(1) This exemption authorizes the transport of packages (freezers) containing infectious substances and/or diagnostic specimens between three Merck & Co. Inc. facilities located in Southeastern Pennsylvania using a specialized, dedicated transport vehicle. Each facility is located within 16 miles of the other two facilities. Packages must be prepared, transported, and unpacked by Pacific Bio-Material Management, Inc. Packages must be transported during low volume traffic hours on low risk routes.

(2) Transport must be made by specially trained personnel in a dedicated, specially-equipped transport vehicle.

(3) Each freezer must be secured in the transport vehicle to prevent movement.

(4) Not more than two freezers may be transported in the transport vehicle.

(5) An itemized list of contents must be securely attached to the outside of each freezer.

(6) Not more than seven shipments are authorized per year (12 consecutive months).

(7) All conditions specified in the Bio-Material Management application must be met.

8. SPECIAL PROVISIONS: A current copy of this exemption must be maintained at each facility where the package is offered or reoffered for transportation.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle

10. MODAL REQUIREMENTS: A current copy of this exemption must be carried aboard each motor vehicle used to transport packages covered by this exemption.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this exemption and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:

- o All terms and conditions prescribed in this exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
- o Persons operating under the terms of this exemption must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this exemption, including display of its number, when this exemption has expired or is otherwise no longer in effect.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this exemption are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this exemption must notify the Associate Administrator for Hazardous Materials Safety -- OHMEA, in writing, of any incident involving a package, shipment or operation conducted under terms of this exemption.

Issued in Washington, D.C.



Robert A. McGuire
Associate Administrator for
Hazardous Materials Safety

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Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, Department of Transportation, Washington, D.C. 20590. Attention: PHH-31.

Copies of this exemption may be obtained by accessing the Hazardous Materials Safety Homepage at <http://hazmat.dot.gov/exemptions> Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

PO: GEC/AM